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(19) (CA) APPLICATION FOR CANADIAN PATENT (12)

(54) Effervescent Cold or Sinus Allergy Medicine Composition  
Having Reduced Sodium Content

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ABSTRACT OF THE DISCLOSURE

An effervescent cold or sinus allergy medicine composition having reduced sodium content is produced from a mixture of an analgesic, such as acetylsalicylic acid, acetaminophen, ketoprofen, or a mixture thereof, citric acid, sodium bicarbonate, calcium carbonate, potassium bicarbonate, antihistamine, decongestant, and minor amounts of flavors and sweeteners.

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- 1 -

EFFERVESCENT COLD OR SINUS ALLERGY MEDICINE  
COMPOSITION HAVING REDUCED SODIUM CONTENT

BACKGROUND OF THE INVENTION AND PRIOR ART

Effervescent cold medicine compositions containing acetylsalicylic acid as an analgesic component, sodium bicarbonate as an antacid component, citric acid and sodium bicarbonate as the principal ingredients of an effervescent couple, and also containing decongestants and/or antihistamines have been known for many years. As used herein, the expression "cold or sinus allergy medicine" is intended to mean a composition useful for relief of the symptoms of head colds, common flu, sinus congestion and hay fever. One disadvantage of these compositions is the elevated sodium content which renders them unsuitable for individuals who should reduce their sodium intake. While efforts have been made in the prior art to produce effervescent compositions having reduced sodium content by including calcium carbonate and potassium bicarbonate, for example, the resulting products form solutions that

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1 have an unpleasant taste. When acetaminophen, which  
has an unpleasant taste itself, is used to replace  
all or a part of the acetylsalicylic acid as the  
analgesic component, the resulting product has been  
5 generally unacceptable from a taste standpoint.

Another problem with prior art effervescent  
compositions having reduced sodium content is that  
they do not completely dissolve. They form a cloudy  
or milky solution with a scum of undissolved parti-  
10 cles floating on the surface of the liquid.

Ketoprofen is another analgesic compound that is  
suitable for use in an effervescent cold or sinus  
allergy medicine composition.

There is thus a need for an effervescent cold or  
15 sinus allergy medicine composition containing decon-  
gestants and/or antihistamines, acetylsalicylic acid,  
acetaminophen, ketoprofen or mixtures thereof as the  
analgesic component and reduced sodium content in the  
effervescent couple/antacid component which forms a  
20 solution that is pleasant tasting. There is also a  
need for such composition that will substantially  
completely dissolve in water to form a clear solution  
with no scum on the liquid surface. There is a  
further need for such composition containing an  
25 antitussive.

U.S. Patent No. 3,495,001 discloses a sodium-  
free effervescent analgesic composition. U.S. Patent  
Nos. 2,854,377; 2,953,459; 2,985,562; 3,102,075;  
3,105,792; 3,136,692; 3,243,377; 3,518,343;  
30 3,903,255; and 4,093,710 disclose various efferves-  
cent compositions containing various amounts and  
combinations of glycine, surfactants such as dioctyl

1 sodium sulfosuccinate, fumaric acid and polyvinyl  
pyrrolidone. I.R.Mohrle, "Pharmaceutical Dosage  
Forms: Tablets", Vol. 1, Marcel Dekker, Inc., New  
York, NY, pp. 225-258 (1980) provides a full de-  
5 scription of various effervescent tablet formulations  
and their ingredients. U.S. Patent No. 4,704,269  
discloses an effervescent analgesic antacid composi-  
tion having reduced sodium content wherein the  
antacid and a food grade acid reactive therewith to  
10 form the effervescent couple are in the form of an  
agglomerate held together by a water soluble food  
grade binder. U.S. Patent No. 4,083,950 discloses an  
effervescent analgesic composition containing  
phenylpropanolamine tartrate and/or bitartrate salt  
15 as a decongestant and chlorpheniramine maleate as an  
antihistamine.

None of the above prior art disclosures specif-  
ically disclose or suggest the novel compositions of  
the present invention.

20

#### SUMMARY OF THE INVENTION

According to this invention, there is provided  
an effervescent cold or sinus allergy medicine  
composition having a reduced sodium content which is  
capable of being dissolved in water to form a pleas-  
25 ant tasting solution which comprises a mixture of  
0.2-16% acetylsalicylic acid, acetaminophen, keto-  
profen or mixtures thereof, 24-38% citric acid,  
12-19% sodium bicarbonate, 8-13% calcium carbonate,  
9-14% potassium bicarbonate, 0.05-0.1% antihistamine,  
30 0.1-1.2% decongestant, 0-0.6% antitussive, 0-11%

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- 1 glycine, 0.8-1.3% flavors and sweeteners, 0-33%  
tableting aids other than lubricants, and 0-6% tablet  
lubricant other than acetylsalicylic acid, said  
percents being weight percent based on the total  
5 weight of the composition.

#### DESCRIPTION OF THE INVENTION

Acetylsalicylic acid, acetaminophen, ketoprofen  
or a mixture thereof provides the analgesic component  
of this composition. The antacid component is  
10 provided primarily by a mixture of sodium bicarbon-  
ate, calcium carbonate, and potassium bicarbonate.  
The effervescent couple is provided by citric acid  
reacting with the carbonates and bicarbonates of the  
antacid component.

15 When acetylsalicylic acid, acetaminophen or  
mixture thereof is the analgesic, it is employed in  
an amount to produce a dose containing 325-500 mg. of  
the analgesic. When ketoprofen is the analgesic, it  
is employed in an amount to produce a dose containing  
20 6.25-50 mg. of the analgesic. The calcium carbonate  
should be employed in an amount so as to provide a  
total daily dosage not exceeding 8 g. The calcium  
carbonate is preferably employed in the spray-dried  
form described in U.S. Patent No. 4,650,669. The  
25 potassium bicarbonate is employed in an amount not to  
exceed a total daily dose of 2.5 g. If desired,  
glycine may be employed to achieve a desired level of  
acid neutralizing capacity. The resulting composi-  
tion when dissolved in water produces a pH of 4-6.



1       The product also contains one or more antihis-  
tamines, such as chlorpheniramine maleate, bromphen-  
iramine maleate, and pyrilamine maleate as well as  
5       one or more decongestants, such as phenylpropanol-  
amine tartrate or bitartrate, phenylephrine tartrate,  
and pseudoephedrine sulfate. The corresponding  
hydrochloride salts of these decongestants can be  
used as long as there is no acetylsalicylic acid in  
the composition. These hydrochloride salts cause  
10       instability of the acetylsalicylic acid.

      If desired, the product may also contain an  
antitussive, such as dextromethorphan hydrobromide.

      The taste of the product after it is dissolved  
in water can be improved by including in the compo-  
15       sition minor amounts of flavors, such as lemon,  
grapefruit and orange flavors, as well as sweeteners,  
such as aspartame and calcium or sodium saccharin.  
The aspartame may be used in the form of granules  
containing lactose and a nonionic surfactant as  
20       described in U.S. Patent No. 4,783,331.

      This composition can be used in a powder-  
granulated form or it can be used in the form of  
compressed tablets. In the production of tablets a  
lubricant is necessary for the tablet dies. When a  
25       significant amount of acetylsalicylic acid is present  
in the formulation, it will function as a lubricant.  
When acetylsalicylic acid is not used or is present  
in minor amounts, it is desirable for fumaric acid to  
be used as a lubricant. It is understood, however,  
30       that other well-known tablet lubricants, such as  
adipic acid and sodium benzoate, can also be used.  
It is also preferable to include tableting aids other

1 than lubricants, such as inert fillers or binders.  
Examples of such fillers or binders are sorbitol,  
lactose, mannitol, fructose, sucrose, a co-  
crystallized mixture of 97% sucrose and 3% modified  
5 dextrans or hydroxypropylmethylcellulose. It is  
preferred that the major component of the tableting  
aids other than lubricants be sorbitol.

In order to have a substantially completely  
dissolved product with no scum floating on the liquid  
10 surface, it is preferable to include in the composi-  
tion minor amounts of polyvinyl pyrrolidone, organo-  
polysiloxane (such as dimethyl polysiloxane), and  
dioctyl sodium sulfosuccinate surfactant.

The composition of the present invention con-  
15 tains 0.2-16% of an analgesic selected from the class  
consisting of acetylsalicylic acid, acetaminophen,  
ketoprofen, and mixtures thereof, 24-38% citric acid,  
12-19% sodium bicarbonate, 8-13% calcium carbonate,  
9-14% potassium bicarbonate, 0.05-0.1% antihistamine,  
20 0.1-1.2% decongestant, 0-0.6% antitussive, 0-11%  
glycine, 0.8-1.3% flavors and sweeteners, 0-33%  
tableting aids other than lubricants, and 0- tablet  
lubricant other than acetylsalicylic acid. Prefera-  
bly, the composition contains 0.2-16% acetylsalicylic  
25 acid, acetaminophen, ketoprofen or mixtures thereof,  
24-26% citric acid, 12-13% sodium bicarbonate, 8-9%  
calcium carbonate, 9-10% potassium bicarbonate,  
0.05-0.07% antihistamine, 0.1-0.8% decongestant,  
0-0.6% antitussive, 0-10% glycine, 0.8-0.9% flavors  
30 and sweeteners, 15-33% tableting aids other than  
lubricants, 2-5% fumaric acid, about 0.03% polyvinyl  
pyrrolidone, about 0.02% organopolysiloxane, and

- 1 about 0.002% dioctyl sodium sulfosuccinate. When an  
antitussive is used, it is preferably present in an  
amount of 0.2-0.6%. All of the above percents are  
weight percent based on the total weight of the  
5 composition.

The final form of the composition is produced by  
dry blending all the ingredients. Final tablet forms  
are produced by feeding the above mixture to a tablet  
press in a manner known to those skilled in the art.

- 10 The following example describes production of  
tablets of one form of the preferred composition.

#### E X A M P L E 1

- A 102 kg. quantity of granulated acetaminophen  
(containing 95.6 weight percent acetaminophen, 3.8  
15 weight percent citric acid and 0.6 weight percent  
hydroxypropylmethylcellulose) was passed through a  
Fitzpatrick Comminutor Model D at 4500 rpm. A 90.17  
kg. quantity of glycine was dried at 130° F. (54.44°  
C.) for 16 hr. Potassium bicarbonate granules were  
20 prepared by mixing 90 kg. of potassium bicarbonate  
with 9.9 kg. of 40 weight percent aqueous sodium  
citrate solution in a Littleford-Lodige Mixer and  
then drying the resulting granules at 180° F. (82.22°  
C.) for at least 22 hr. Such granules were then  
25 passed through a Fluid Aire Mill operating at 1500  
rpm. A premix of 0.3 kg. polyvinyl pyrrolidone, 0.15  
kg. dimethyl polysiloxane and 0.015 kg. of dioctyl  
sodium sulfosuccinate (in the form of a mixture  
containing 85 weight percent dioctyl sodium sulfo-  
30 succinate and 15 weight percent sodium benzoate) was

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1 prepared by passing such materials through a Fitz-  
patrick Comminutor Model D at 4700 rpm. A 45 kg.  
quantity of fumaric acid was passed through a Fitz-  
patrick Comminutor Model D at 2500 rpm. A 120 kg.  
5 portion of sodium bicarbonate was heat treated as  
described in U.S. Patent No. 3,105,792. An 11.007  
kg. quantity of aspartame granules (containing 20.44  
weight percent aspartame, 78.61 weight percent  
lactose and 0.95 weight percent nonionic surfactant)  
10 was prepared as described in U.S. Patent No.  
4,783,331. A 101.1 kg. portion of spray-dried  
calcium carbonate (containing 83 weight percent  
calcium carbonate, 9.95 weight percent lactose and  
7.05 weight percent maltodextrin) was prepared as  
15 described in U.S. Patent No. 4,650,669. All of the  
above materials along with 150 kg. sorbitol, 5.01 kg.  
of a mixture of lemon, grapefruit and orange flavors,  
0.9 kg. calcium saccharin, 247.5 kg. anhydrous citric  
acid, 0.6 kg. chlorpheniramine maleate and 7.5 kg.  
20 phenylpropanolamine bitartrate were mixed in an  
Englesmann Mixer at 20 rpm for 14 minutes. The final  
mixture was then fed to a tablet press to produce  
tablets each containing 325 mg. acetaminophen and  
having a composition of:

1	<u>Weight %</u>	<u>Ingredient</u>
	10.00	Acetaminophen
	25.78	Citric Acid
	12.31	Sodium Bicarbonate
5	8.62	Calcium Carbonate
	9.23	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.77	Phenylpropanolamine Bitartrate
	9.25	Glycine
10	0.84	Flavors and Sweeteners
	18.48	Sorbitol and Other Tableting Aids
	4.62	Fumaric Acid
	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
15	<u>0.002</u>	Dioctyl Sodium Sulfosuccinate
	100.012	

When the above tablet product was placed in water, there was significant effervescence while the tablet dissolved resulting in a substantially clear solution with no scum on the liquid surface. This solution had a pleasant taste with no undesirable after-taste.

The following examples describe production of other forms of the composition of this invention.

25                    EXAMPLE 2

The formulation of Example 1 is modified to increase the tablet content of acetaminophen to 500 mg. The sorbitol content is reduced to compensate

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- 1 for this keeping all the other ingredients the same.  
The tablet product has the composition of:

	<u>Weight %</u>	<u>Ingredient</u>
	15.00	Acetaminophen
5	25.35	Citric Acid
	12.00	Sodium Bicarbonate
	8.40	Calcium Carbonate
	9.00	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
10	0.75	Phenylpropanolamine Bitartrate
	9.02	Glycine
	0.82	Flavors and Sweeteners
	15.05	Tableting Aids Other Than Lubricants
15	4.50	Fumaric Acid
	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
	100.002	

20

EXAMPLE 3

- The formulation of Example 1 is used with the direct substitution of acetylsalicylic acid for acetaminophen. The fumaric acid is deleted since the acetylsalicylic acid also functions as a lubricant.
- 25 The sorbitol content is adjusted to maintain a constant tablet weight. The tablets containing 325 mg. acetylsalicylic acid have the composition of:

	<u>Weight %</u>	<u>Ingredient</u>
1	10.00	Acetylsalicylic Acid
	25.38	Citric Acid
	12.31	Sodium Bicarbonate
5	8.62	Calcium Carbonate
	9.23	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.77	Phenylpropanolamine Bitartrate
	9.25	Glycine
10	0.84	Flavors and Sweeteners
	23.50	Tableting Aids Other Than Lubricants
	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
15	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
	100.012	

E X A M P L E 4

The formulation of Example 3 is modified to increase the tablet content of acetylsalicylic acid to 500 mg. The sorbitol content is reduced to compensate for this keeping all the other ingredients the same. The tablet product has the composition of:

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	<u>Weight %</u>	<u>Ingredient</u>
1	15.00	Acetylsalicylic Acid
	24.75	Citric Acid
	12.00	Sodium Bicarbonate
5	8.40	Calcium Carbonate
	9.00	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.75	Phenylpropanclamine Bitartrate
	9.02	Glycine
10	0.82	Flavors and Sweeteners
	20.15	Tableting Aids Other Than
		Lubricants
	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
15	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
	100.002	

# EXAMPLE 5

The formulation of Example 1 is modified to produce a tablet containing 162.5 mg. acetaminophen and 162.5 mg. acetylsalicylic acid. The sorbitol content is adjusted to compensate for this and the fumaric acid is reduced to an amount necessary for adequate lubrication. The tablet product has the composition of:

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1	<u>Weight %</u>	<u>Ingredient</u>
	5.00	Acetaminophen
	5.00	Acetylsalicylic Acid
	25.58	Citric Acid
5	12.31	Sodium Bicarbonate
	8.62	Calcium Carbonate
	9.23	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.77	Phenylpropanolamine Bitartrate
10	9.25	Glycine
	0.84	Flavors and Sweeteners
	20.99	Tableting Aids Other Than Lubricants
	2.31	Fumaric Acid
15	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
	100.012	

E X A M P L E 6

20 The formulation of Example 5 is modified to increase the tablet content of acetaminophen and acetylsalicylic acid each to 250 mg. The sorbitol content is reduced to compensate for this and the fumaric acid is deleted. The tablet product has the  
25 composition of:

	<u>Weight %</u>	<u>Ingredient</u>
1	7.69	Acetaminophen
	7.69	Acetylsalicylic Acid
	25.69	Citric Acid
5	12.31	Sodium Bicarbonate
	8.62	Calcium Carbonate
	9.23	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.77	Phenylpropanolamine Bitartrate
10	9.25	Glycine
	0.84	Flavors and Sweeteners
	17.81	Tableting Aids Other Than Lubricants
	0.03	Polyvinyl Pyrrolidone
15	0.02	Dimethyl Polysiloxane
	<u>0.002</u>	Dioctyl Sodium Sulfosuccinate
	100.012	

E X A M P L E    7

The formulation of Example 3 is modified to  
 20 remove the glycine and the tableting aids. The  
 product has the composition of:

	<u>Weight %</u>	<u>Ingredient</u>
1	14.87	Acetylsalicylic Acid
	37.74	Citric Acid
	18.30	Sodium Bicarbonate
5	12.81	Calcium Carbonate
	13.72	Potassium Bicarbonate
	0.09	Chlorpheniramine Maleate
	1.14	Phenylpropanolamine Bitartrate
	1.24	Flavors and Sweeten :s
10	0.05	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
	99.982	

E X A M P L E 8

- 15 The formulation of Example 3 is modified to remove the glycine but retain tableting aids. The overall tablet weight is the same. The product has the composition of:

1	<u>Weight %</u>	<u>Ingredient</u>
	10.0	Acetylsalicylic Acid
	25.38	Citric Acid
	12.31	Sodium Bicarbonate
5	8.62	Calcium Carbonate
	9.23	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.77	Phenylpropanolamine Bitartrate
	0.84	Flavors and Sweeteners
10	32.75	Tableting Aids Other Than
		Lubricants
	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
15	100.012	

E X A M P L E 9

The formulation of Example 1 is modified to remove the glycine but retain tableting aids. The overall dose weight is the same. The product has the composition of:

1	<u>Weight %</u>	<u>Ingredient</u>
	10.00	Acetaminophen
	25.78	Citric Acid
	12.31	Sodium Bicarbonate
5	8.62	Calcium Carbonate
	9.23	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.77	Phenylpropanolamine Bitartrate
	0.84	Flavors and Sweeteners
10	27.73	Tableting Aids
	4.62	Fumaric Acid
	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
15	100.012	

EXAMPLE 10

The formulation of Example 1 was modified to substitute brompheniramine maleate for the chlorpheniramine maleate as the antihistamine. The other ingredients remained the same.

EXAMPLE 11

The formulation of Example 1 is modified to substitute 6.25 mg. ketoprofen for 325 mg. acetaminophen. The other ingredients remain the same. The tablet product has the composition of:

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	<u>Weight %</u>	<u>Ingredient</u>
1	0.21	Ketoprofen
	28.29	Citric Acid
	13.72	Sodium Bicarbonate
5	9.60	Calcium Carbonate
	10.29	Potassium Bicarbonate
	0.07	Chlorpheniramine Maleate
	0.86	Phenylpropanolamine Bitartrate
	10.31	Glycine
10	0.93	Flavors and Sweeteners
	20.53	Tableting Aids
	5.14	Fumaric Acid
	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
15	<u>0.002</u>	Dioctyl Sodium Sulfosuccinate
	100.002	

#### E X A M P L E 12

The formulation of Example 11 is modified to increase the ketoprofen content to 50 mg. The other ingredients remain the same.

#### E X A M P L E 13

The formulation of Example 1 is modified to include an antitussive dextromethorphan hydrobromide. The tablet product has the composition of:

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1	<u>Weight %</u>	<u>Ingredient</u>
	10.00	Acetaminophen
	25.78	Citric Acid
	12.31	Sodium Bicarbonate
5	8.62	Calcium Carbonate
	9.23	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.77	Phenylpropanolamine Bitartrate
	0.31	Dextromethorphan Hydrobromide
10	9.25	Glycine
	0.84	Flavors and Sweeteners
	18.16	Sorbitol and Other Tableting Aids
	4.62	Fumaric Acid
	0.03	Polyvinyl Pyrrolidone
15	0.02	Dimethyl Polysiloxane
	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
	100.002	

E X A M P L E 14

The formulation of Example 4 is modified to  
 20 include dextromethorphan hydrobromide. The tablet  
 product has the composition of:

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1	<u>Weight %</u>	<u>Ingredient</u>
	15.00	Acetylsalicylic Acid
	24.75	Citric Acid
	12.00	Sodium Bicarbonate
5	8.40	Calcium Carbonate
	9.00	Potassium Bicarbonate
	0.06	Chlorpheniramine Maleate
	0.75	Phenylpropanolamine Bitartrate
	0.45	Dextromethorphan Hydrobromide
10	9.02	Glycine
	0.82	Flavors and Sweeteners
	19.70	Tableting Aids
	0.03	Polyvinyl Pyrrolidone
	0.02	Dimethyl Polysiloxane
15	<u>0.002</u>	Diethyl Sodium Sulfosuccinate
	100.002	

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WHAT IS CLAIMED IS:

1           1. A sodium-containing effervescent cold or  
sinus allergy medicine composition having a reduced  
sodium content as compared to prior art compositions  
which is capable of being dissolved in water to form  
5 a pleasant tasting solution which comprises a mixture  
of 0.2-16% of an analgesic selected from the class  
consisting of acetylsalicylic acid, acetaminophen,  
ketoprofen, and mixtures thereof, 24-38% citric acid,  
12-19% sodium bicarbonate as the only sodium-  
10 containing active ingredient, 8-13% calcium carbon-  
ate, 9-14% potassium bicarbonate, 0.05-0.1% antihis-  
tamine, 0.1-1.2% decongestant, 0-0.6% antitussive,  
0-11% glycine, 0.8-1.3% flavors and sweeteners, 0-33%  
tableting aids other than lubricants, and 0-6% tablet  
15 lubricant other than acetylsalicylic acid, said  
percents being weight percent based on the total  
weight of the composition.

1           2. A composition of Claim 1 suitable for  
forming tablets which are capable of being dissolved  
in water to form a pleasant tasting solution which  
contains 15-33% tableting aids other than lubricants  
5 and 2-6% tablet lubricant other than acetylsalicylic  
acid.

1           3. A composition of Claim 2 which also contains  
about 0.03-0.05% polyvinyl pyrrolidone, about 0.02%  
organopolysiloxane and about 0.002% dioctyl sodium  
sulfosuccinate.

1           4. A composition of Claim 2 wherein the major  
component of the tableting aids is sorbitol and the  
tablet lubricant is fumaric acid.

1           5. An effervescent cold or sinus allergy  
medicine composition having a reduced sodium content  
as compared to prior art compositions suitable for  
forming tablets which are capable of being substan-  
5           tially completely dissolved in water forming a  
pleasant tasting solution which consists essentially  
of a mixture of 0.2-16% of an analgesic selected from  
the class consisting of acetylsalicylic acid, aceta-  
minophen, ketoprofen, and mixtures thereof, 24-26%  
10          citric acid, 12-13% sodium bicarbonate, 8-9% calcium  
carbonate, 9-10% potassium bicarbonate, 0.05-0.07%  
antihistamine, 0.1-0.8% decongestant, 0-0.6%  
antitussive, 0-10% glycine, 0.8-0.9% flavors and  
sweeteners, 15-33% tableting aids other than lubri-  
15          cants, 2-5% fumaric acid, about 0.03% polyvinyl  
pyrrolidone, about 0.02% organopolysiloxane, and  
about 0.002% dioctyl sodium sulfosuccinate, said  
percents being weight percent based on the total  
weight of the composition.

1           6. A composition of Claim 5 wherein the anti-  
histamine is chlorpheniramine maleate, bromphen-  
iramine maleate or mixtures thereof and the decon-  
gestant is phenylpropanolamine bitartrate or tar-  
5           trate.

1           7. A composition of Claim 5 wherein the anal-  
gesic is acetaminophen.

- 1        8. A composition of Claim 5 wherein the anal-  
gesic is acetylsalicylic acid.
- 1        9. A composition of Claim 5 wherein the anal-  
gesic is a mixture of acetaminophen and acetylsali-  
cylic acid.
- 1        10. A composition of Claim 5 wherein the  
analgesic is ketoprofen.
- 1        11. A composition of Claim 5 containing  
0.2-0.6% antitussive.
- 1        12. A composition of Claim 11 wherein the  
antitussive is dextromethorphan hydrobromide.

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